



11-08-05

ifw

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/696,384
Filing Date	October 29, 2003
First Named Inventor	Mahesh Chaubal
Art Unit	1615
Examiner Name	Simon Oh
Attorney Docket Number	IFT-5657A-1A1C6 (3360.0003.02)

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): - Forms PTO/SB/08A and /08B - 40 cited references - Certificate of Mailing - Return Postcard
<div>Remarks</div>		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Cook, Alex, McFarron, Manzo, Cummings & Mehler, Ltd.		
Signature			
Printed name	Raymond M. Mehler		
Date	November 7, 2005	Reg. No.	26,306

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature			
Typed or printed name	Barbara Gesiakowski	Date	November 7, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

American LegalNet, Inc.  
www.USCourtForms.com



PATENT  
Attorney Docket No. IFT-5657A-1A1C6 (3360-0003.02)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of: )

Mahesh Chaubal et al. )

Serial No.: 10/696,384 )

Filed: October 29, 2003 )

Group Art No.: 1615 )

Examiner: Simon Oh )

For: PROCESS FOR PRODUCTION OF )  
ESSENTIALLY SOLVENT-FREE )  
SMALL PARTICLES )

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

"Express Mail" Mailing Label No. EV643274635US

Date of Deposit November 7, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office Box Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450

NAME Barbara Gesiakowski

SIGNATURE B. Gesiakowski

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Certificate of Mailing Under 37 CFR 1.10**

I hereby certify that the correspondence listed below is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, **Label No. EV 643274635 US** under 37 CFR 1.10 on **November 7, 2005** and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

1. Transmittal Form PTO/SB/21 (1 sheet);
2. Information Disclosure Statement (3 sheets);
3. PTO/SB/08A and /08B (4 sheets);
4. Foreign Patent Documents and Non-Patent Publications (40 Documents)
5. Certificate of Mailing (1 sheet); and
6. Return Receipt Postcard.

Name: Barbara Gesiakowski

Signature: B. Gesiakowski



PATENT

Attorney Docket No. IFT-5657A-1A1C6 (3360-0003.02)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of: )

Mahesh Chaubal et al. )

Serial No.: 10/696,384 )

Filed: October 29, 2003 )

Group Art No.: 1615 )

Examiner: Simon Oh )

For: PROCESS FOR PRODUCTION OF )  
ESSENTIALLY SOLVENT-FREE )  
SMALL PARTICLES )

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

"Express Mail" Mailing Label No. EV643274635US

Date of Deposit November 7, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office Box Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450

NAME Barbara Gesiakowski

SIGNATURE B. Gesiakowski

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants hereby call the Examiner's attention to documents listed on the attached forms, which documents may be material to the examination of this application. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue

therefrom.

Copies of the U.S. patents and U.S. patent publications are not enclosed pursuant to the Office's waiving of the requirement under 37 C.F.R. §1.98, paragraph (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication. Copies of the foreign patents and publications other than U.S. patents and U.S. patent application publications are enclosed, pursuant to 37 C.F.R. 1.98(2)(i) and (2)(ii).

No inference should be drawn that any apparatus or method disclosed is equivalent to the subject invention. Also, the citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

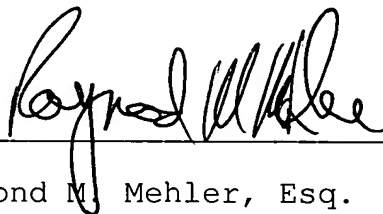
Applicants also respectfully reserve the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the present patent application.

This Information Disclosure Statement is being submitted within three months of the filing date of the application or before the receipt of a first Office Action on the merits. Consequently, as provided in 37 C.F.R. § 197(b)(1) or (b)(3), a fee under § 1.17(p) is not required for the filing of this information disclosure. However, if it is determined that an additional fee is required, then authorization is hereby granted to charge Deposit Account 50-1039 any additional fee required. (A duplicate of this document is enclosed herewith.)

Respectfully submitted,

Date: November 7, 2005

By:

A handwritten signature in black ink, appearing to read "Raymond M. Mehler", is written over a horizontal line.

Raymond M. Mehler, Esq.  
Registration No. 26,306  
Cook, Alex, McFarron, Manzo,  
Cummings & Mehler, Ltd.  
200 West Adams St., Suite 2850  
Chicago, IL 60606  
Telephone: (312) 236-8500  
Attorneys for Applicant



Application Number	10/696,384
Filing Date	October 29, 2003
First Named Inventor	Mahesh Chaubal
Art Unit	1615
Examiner Name	Simon Oh
Attorney Docket Number	IFT-5657A-1A1C6 (3360-0003.02)

**American LegalNet, Inc.**  
**www.USCourtForms.com**

Under the Paperwork Reduction Act of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/696,384
Filing Date	October 29, 2003
First Named Inventor	Mahesh Chaubal
Art Unit	1615
Examiner Name	Simon Oh
Attorney Docket Number	IFT-5657A-1A1C6 (3360-0003.02)

Sheet 3

of

4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	40	ALLEN, T.M. et al., "Large unilamellar liposomes with low uptake into the reticuloendothelial system", Elsevier Science Publishers B.V., Vol 223, No. 1, pp. 42-46, October, 1987.	
	41	ALLEN, T.M. et al., "Effects on the murine mononuclear phagocyte system of chronic administration of liposomes containing cytotoxic drug or lipid A compared with empty liposomes", Vol 65, pp. 185-190, 1987.	
	42	AQUARO, et al. Antiviral Research 55, pp. 209-225, 2002.	
	43	BENDER et al., "Efficiency of Nanoparticles as a Carrier for Antiviral Agents in Human Immunodeficiency Virus-Infected Human Monocytes/Macrophages In Vitro", Antimicrobial Agents and Chemotherapy, 40(6), pp. 1467-1471, June 1996.	
	44	CROWE, et al., Journal of Leukocyte Biology, pp. 635-641, November 2003.	
	45	FISCHER-SMITH, et al., Journal of NeuroVirology, 7, pp. 528-541, 2001.	
	46	GRAHAM, D.T., et al., "The Effects of Freezing on Commercial Insulin Suspensions", International Journal of Pharmaceutics, 1978.	
	47	KINMAN et al., Journal of Acquired Immune Deficiency Syndrome, 34(4), pp. 387-397, December 1, 2003.	
	48	LIMOGES et al., poster presentation, 11th Conference on Retroviruses and Opportunistic Infections, February 8-11, 2004.	
	49	MOGHIMI et al., Pharmacological Reviews, 53, pp. 283-318, 2001.	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/696,384
Filing Date	October 29, 2003
First Named Inventor	Mahesh Chaubal
Art Unit	1615
Examiner Name	Simon Oh
Attorney Docket Number	IFT-5657A-1A1C6 (3360-0003.02)

Sheet

4

of

4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	50	NESBIT et al., Clinical and Diagnostic Laboratory Immunology, 9(3), pp. 515-524, May 2002.	
	51	NOTTET et al., The Neurology of AIDS, p. 55, 1998.	
	52	PERNO et al., The Journal of Infectious Diseases, 178, pp. 413-422, 1998.	
	53	SAWCHUK et al., Advanced Drug Delivery Reviews, 39, pp. 5-31, 1999.	
	54	SCHROEDER, H.G., "Distribution of Radiolabeled Subdivisible Microspheres after Intravenous Administration to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol 67, No 4, pp. 504-507, April 1978.	
	55	SHRAYER, D. et al., "Ceramide, a mediator of apoptosis, synergizes with paclitaxel to induce regression of the L3.6 human pancreatic carcinoma implanted in SCID mice", Journal of Clinical Oncology, Vol 22, No 14S (July 15 Supplement), 2004: 2135.	
	56	SOLAS et al., Antimicrobiology Agents and Chemotherapy, 47 (1), pp. 238-243, January 2003.	
	57	VON BRIESEN, H., "Controlled Release of Antiretroviral Drugs", AIDS Rev., 2, pp. 31-38, 2000.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.